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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,751	10/19/2001	Lionel Breton	016800-461	6150

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EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,751	BRETON ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 24-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 24-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/572,234* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 4 filed Nov. 04, 2002 have been considered but they are not persuasive for the reasons below(see 102 rejection).

2. Additionally, Newly amended and added claims are moot in view of the new ground(s) of rejection because of the changes made in the scope of the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 is unclear whether the recited limitation "for smoothing the skin" is further limiting previous claim 1 or not. The phrase "for smoothing the skin" has not been recited in claim 1.

The claim 4 is dependent on claim 1 and supposedly further limiting the subject matter of the previous claim which is "for loosening and/or relaxing". However, Smoothing the skin is not necessarily encompassed by the term "loosening and/or relaxing". The phrase "smoothing skin" would have been acknowledged in the art as opposite meaning to the phrase "loosening/relaxing skin tissue" , see US 6,440,433(Breton et al) or US6413255(Stern) wherein each patentee use the term " a loosening or relaxing of skin" is functional equivalent or causative mechanism to the wrinkled skin and fine lines whereas smooth skin is healthy and preferred looking skin which is treated from wrinkled skin, see column 1, lines 60-65(US'433) and column 18, 50-65. Thus, it is not clear what applicant's intention is by reciting "smoothing skin".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4 and 24-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US patent 5,569,678).

Lee teaches a method for minimizing or preventing excessive scar formation(e.g. hypertophic scars and keloids). For instance, in his patented disclosure, Lee teaches the biological pathway involving fibroblast. In normal wound healing process, fibroblasts contact the collagen in order to reduce the surface area of the wound which usually associated with enlarger surface area than normal skin due to tear, split, or damages, via increased mechanical tension and strength, see column 1, lines 25-55. Thus, excessive fibroblasts are responsible for the scar tissue formation wherein the skin has aesthetic deformity due to excessively high tension and strength to reduce the surface area than normal skin. Calcium channel antagonist could effectively decreases fibroblast biosynthesis and decrease the collagen content and stimulate the collagenase activity, see column 4, lines 1-5. Lee further teaches that softening and fading scar tissues(normalizing into the intact skin tissue membrane) can also be achieved via changing the cell shapes and viabilities to rounder(see column 11, lines 45-47) and more viable, respectively(see, column 4, lines 25-61). Thus, one would have been envisaged the therapeutic effects are resulted from loosening and/or relaxing skin

tissues from excessively tightened skin tissues so that the surface of scarred area could be softened and faded away.

As to the limitation(i.e. musclular decontraction and/or relaxation) recited in preamble, it is noted that it is well known in the art that calcium channel antagonists are muscle relaxant, which is also evidenced by applicant's own admission(see page 2, lines 18-21 in the instant specification). Thus, the muscle relaxing effect is inherently achieved when Lee's patented composition is applied to affected area to maximize softening and minimizing the scar tissues. The claimed subject matter(i.e. loosening and relaxing the skin tissues) is envisaged and thus, the instant claims are anticipated by the cited reference.

As to claim 4, one would have envisaged that the smoothing the skin is naturally achieved by the treatment taught by the Lee's patent because Lee teaches that said treatment (i.e. verapamil treatment, see column 11, example 4) regulates the skin cells to rounder, viable and into the intact skin cell membranes(round) where the texture of natural intact skin would be smooth(see column 4). Thus, the instant claim 4 is properly included in this rejection.

As to claims 24-31, all the critical elements, for instance, inhibition of calcium/calmodulin complex, dihydropyridine(nifedipine), verapamil, benzothiazepine(diltiazem), a calmodulin antagonist, trifluoperazine, subcutaneous or intradermal injection are taught by the cited reference(see column 3, lines 40-65 and claims). It is noted that it is notoriously known that the injection into the wound site(see

patented claim 20) would be performed subcutaneously or intradermally and thus, claim 31 is properly included in this rejection.

All the critical elements are taught by the cited reference wherein Lee teaches that calcium channel antagonists are effectively used in softening scar tissue; restoring aesthetic deformity of skin; regulating cell shape and controlling wound scar production by minimizing, preventing or reversing the scar tissue via normalizing the scar tissue to the intact tissue membrane which is smooth and loosened/relaxed when the texture is compared to the scar tissues. And thus, the claims are anticipated and properly included in this rejection.

In response to the applicant's argument that allegedly states that Lee's teaching is directly contrast to the present invention because Lee contemplates his invention via reducing surface area of the skin whereas the instant invention is directed to loosening/relaxing skin tissues which results in enlarging surface area. This examiner does not accept this allegation because Lee's teaching is directed to a method of reducing or preventing scar tissues or scar formation by normalizing the skin cell and tissues to intact tissue membrane via loosening/ relaxing the excessively tightened surface and smoothing/remodeling the abnormal and deformed skin tissues so that the scar tissue becomes normal and healthy tissue.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al in view of Perricone (US 5965618) or Lew(abstract only, 1995).

Lee's teaching is mentioned in 102 rejection(supra).

Applicant's claims differ because they require keratolyric agent(i.e. alpha or beta hydroxy acids or retinoid).

Perricone teaches a scar tissue treatment using lipoic acid and alpha hydroxy acid(e.g. lactic or glycolic acid) to enhance the efficacy of diminishing the scar tissues, see column 1, lines 27-37 and column 6, lines 5-45.

Lew teaches a retinoid as an effective compound used in wound healing and prevention of scar tissues, see entire abstract.

Thus, it would have been obvious to one of ordinary skill in the art to add alpha hydroxy acid to enhance therapeutic and prophylactic efficacy of scar tissue removal wherein the loosening/relaxing skin tissue is naturally occurred and the effectiveness is enhanced when these references are taken together. Thus one would have motivated to do so, with reasonable expectation of success, because the effectiveness and safety of skin treatment containing alpha or beta hydroxy-acid or retinoid is well proven and documented, and thus preparation of this enhanced formulation could be obtained relatively easy and cheaper without serious side effects.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or

similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 4, 24-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,344,461. Although the conflicting claims are not identical, they are not patentably distinct from each other because one would have expected the beneficial skin effects by using calcium channel inhibitors. As evidenced by applicant's own admission(see page I) where applicant states that the mechanism of loosening/relaxing skin tissue is used for treating wrinkles and fine lines, US'461 claims inherently possess the effect of loosening/relaxing skin tissue, and thus, the claimed subject matter is achieved when the treatment of wrinkles or fine lines and the microrelief on the

skin tissue is contemplated by using calcium channel inhibitors as patented. Thus, this double patenting rejection is maintained.

Conclusion

9. All the pending claims 1, 4 and 24-33 are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
January 29, 2003
Art unit 1614

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SUPERVISORY PATENT EXAMINER
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